



FOOD AND DRUG SAFETY PROGRAM

**2011
ANNUAL REPORT**

**Food and Drug Safety Program
NJDHSS
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MISSION STATEMENT

The Food and Drug Safety Program's mission is to:

- Enforce the State's food, drug, and cosmetic laws
- Reduce the incidence of foodborne illness
- Promote consumer food safety
- Provide technical support to the food industry and local health departments in matters regarding food safety and food defense

The Program is divided into 6 major project areas:

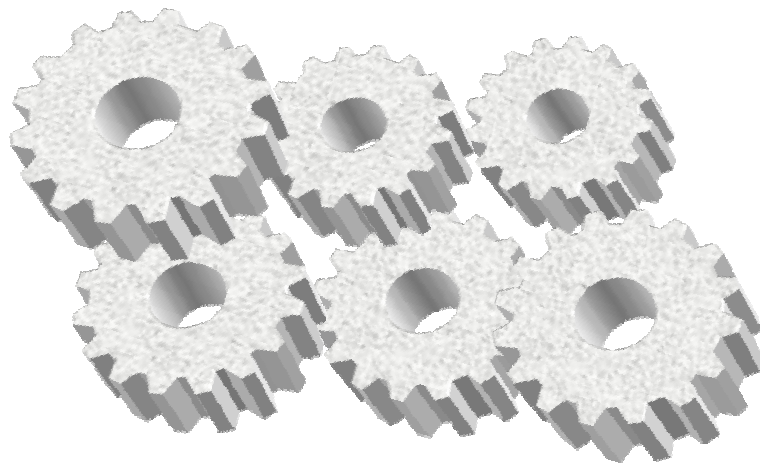
- Wholesale Food and Cosmetics
- Retail Food
- Seafood and Shellfish
- Food Emergency Preparedness and Defense
- Dairy, Bottled Water, and Juice
- Wholesale Drug

UNIFYING PRINCIPLES

QUALITY

**TECHNICAL
COMPETENCE**

INTEGRITY



PROACTIVITY

**CLIENT
SERVICES**

RESPONSIVENESS

INTRODUCTION

Advances in science, societal changes, increasing complexity of products and manufacturing processes, and the impact of globalization on food supply chains have led to countless issues, opportunities, and threats that were unimaginable just a generation ago. Today, 15-20% of food consumed by Americans is imported, including nearly 60% of fresh produce and 80% of seafood. With increasingly longer supply chains that cross international borders, protection of food and public health has become much more complex.

In 2011 the Food and Drug Safety Program (FDSP), in partnership with the U.S. Food and Drug Administration (FDA), began a food defense initiative at the Met Life Stadium. The Stadium, which has been selected to host the 2014 Super Bowl, was identified by the FBI as a potential target for terrorist attack. The initiative focused only on food defense concerns associated with in-State and out-of-State wholesale food establishments supplying food to the Stadium and the food services within the Stadium. FDSP discussed food defense with corporate and the foodservice management company, conducted three on-site visits to assess food defense vulnerabilities, and provided recommendations to key management personnel. FDSP inspectors also conducted food defense investigations of the Stadium's wholesale suppliers.

For 2012, the FDSP looks forward to strengthening food defense activities at major sports and entertainment centers, as well as schools and synagogues. It is noteworthy that the FDSP's food defense filed initiatives at the wholesale level decreased from 541 in 2010 to 30 in 2011.

In 2011, FDSP elected to participate in FDA's Manufactured Foods Regulatory Program Standards. The Standards establish a uniform foundation for the design and management of State programs responsible for the regulation of food plants and describe best practices of a high quality food inspection program. This is an elective activity in the FDA Contract. FDA is offering states over \$100,000 to implement the Standards.

The multi-state outbreak associated with *Listeria* in cantaloupes from a farm in Colorado caused 32 fatalities and 146 illnesses, according to the Centers for Disease Control and Prevention (CDC). Some of these cantaloupes reached New Jersey consumers. In the midst of the outbreak, FDSP staff worked closely with FDA to ensure any affected products were removed from the marketplace.

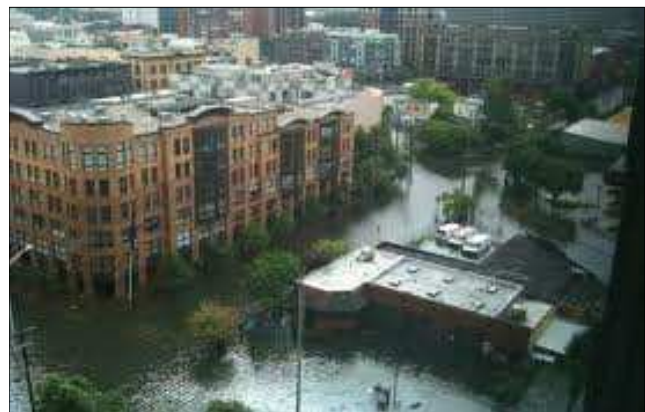
Inspectional efforts, however, have been dramatically affected by the sagging economy and a drastic reduction in staff. Consequently, the FDSP has experienced a reduction in the number of inspections performed. For example, in 2006 a total of 1,083 wholesale inspections were completed, while only 640 wholesale inspections were completed in 2011. That represents a sharp 41% decrease. Retail inspections completed in 2006 totaled 1,160, but in 2011, the total was 852 (27% decrease). Dwindling staff has forced the program to shift priorities. For example, the FDSP's on-going standardization training program takes intervention to a higher level, training local and State inspectors statewide to focus on high-risk foods and practices. This signifies more of a quality, than quantity approach that enables inspectors to do their jobs effectively without sacrificing public health.

The FDSP has also enhanced educational outreach efforts to local health departments, members of the industry, and consumers. In 2011, local health departments benefitted from the Program's numerous trainings on topics such as imported food safety, packaged food labeling, and food defense at seminars and conferences. Industry educational outreach included roll-out of the "Guidance

Document for Emergency Action Planning for Retail Food Establishments,” a comprehensive emergency preparedness and response guide for restaurants, grocery stores, and other retail food establishments. The roll out of this guidance document was key for the successful response to Hurricanes Irene and Lee, where Operation Food Distribution was activated.

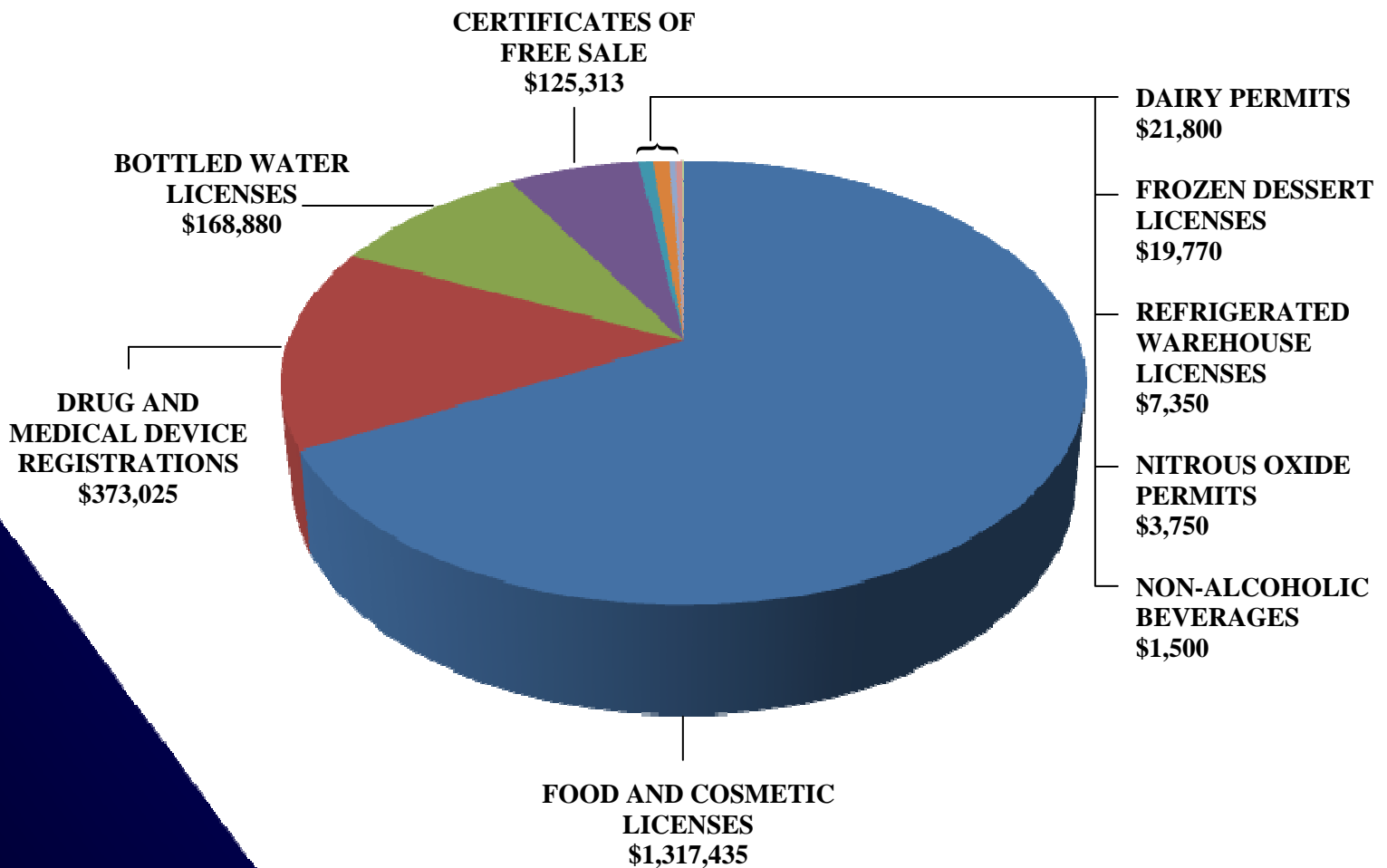
Prior to the arrival of Hurricane Irene, FDSP sent out guidance and reminders to help the NJ food industry prepare, respond, and recover from hurricane damages as part of joint efforts to ensure that only safe and wholesome foods enter the marketplace. As a follow-up to Hurricane Irene and subsequent storms, 10 FDSP staff members volunteered to work with Local Health Departments (LHDs) to provide guidance regarding retail food establishments operating under limited operations because of damages from the hurricane. The FDSP had more volunteers than any other service program. Staff members provided much-needed information and advice to members of the public on topics such as food/water safety, mold remediation, carbon monoxide detection, sewage spill clean ups, and sanitation of household items that came into contact with sewage water. Staff worked approximately 10 hours per day at the centers. They also provided direct assistance by conducting retail food inspections for LHDs. They worked side by side with the Office of Emergency Management (OEM), and the regulated food industry following the activation of Operation Food Distribution (OFD) as part of the State’s Emergency Operations Plan. The purpose of OFD is to feed the public following a widespread emergency by using the private sector. This Operation is a great example of the public and private sector working in partnership to serve the needs of the public.

In summary, despite dwindling resources, food safety innovations now and into the future will remain paramount in order to ensure a safe and wholesome food supply.



SUMMARY OF PROGRAM REVENUE AND DISTRIBUTION

The Program maintains and collects a total of nine revenue streams through licensures, permits, registrations, and certificates. The table below illustrates the total funds we collected for each revenue category in 2011.



TOTAL REVENUE FOR 2011:
\$2,038,823

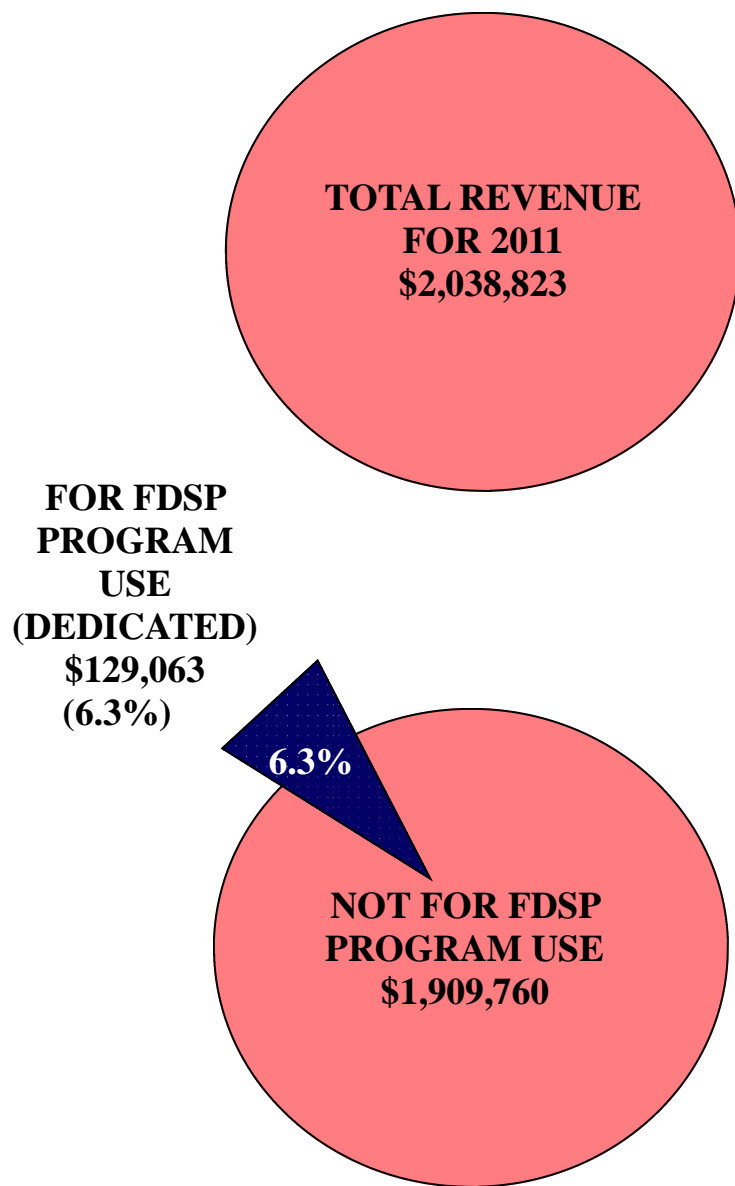
PROGRAM REVENUE AND DISTRIBUTION

Listed below are the revenue sources for the \$2,038,823 collected in 2011. The purpose of the chart is to illustrate the limited allocation of funds to directly support Program functions.

SOURCES OF REVENUE

- **FOOD/COSMETIC LICENSES**
- **DRUG/MEDICAL DEVICE REGISTRATIONS**
- **DAIRY PERMITS**
- **REFRIGERATED WAREHOUSE LICENSES**
- **NON-ALCOHOLIC BEVERAGE LICENSES**
- **BOTTLED WATER LICENSES**
- **CERTIFICATES OF FREE SALE**
- **NITROUS OXIDE PERMITS**

DISTRIBUTION



SUMMARY OF LICENSING AND ACTIVITIES

LICENSES, REGISTRATIONS, PERMITS, VERIFICATIONS, AND CERTIFICATIONS						
	2011	2010	2009	2008	2007	2006
Food and cosmetic licenses	2,308	2,273	1,909	2,303	1,840	2,482
Drug and medical device registrations	1,545	1,450	1,126	1,280	1,093	1,101
GMP and Certificates of Free Sale	2,381	2,268	2,117	1,839	1,631	1,480
Drug verifications	2,092	1,000	746	621	600	300
Shellfish certificates	135	149	150	146	145	153
Nitrous oxide permits	151	147	127	664	264	113
Bottled water licenses	216	231	173	197	196	130
Milk and frozen dessert licenses	322	398	311	401	257	506
Refrigerated warehouse licenses	36	33	30	36	39	36
Non-alcoholic beverage licenses	42	41	28	43	44	10
TOTAL	9,228	7,990	6,717	7,530	6,109	6,311
WORK ACTIVITIES						
	2011	2010	2009	2008	2007	2006
Wholesale food and cosmetic inspections and investigations	640	605	736	870	1,063	1,083
Food sampling	854	774	655	732	1,126	1,144
Retail inspections	852	783	850	950	1,100	1,160
Wholesale food defense industry site visits	30	395	520	580	818	998
Shellfish inspections	392	435	445	385	335	335
Bottled water, dairy, frozen dessert, and juice inspections	277	239	216	325	269	238
Seafood HACCP inspections	50	50	50	50	50	50
Food defense surveys completed for best practices implementation	0	146	238	284	269	27
Critical infrastructure assessments	0	0	1	1	0	0
Wholesale drug inspections	3	0	0	0	0	0
Embargo Activities	17	10	14	50	14	76
TOTAL	3,085	3,437	3,725	4,227	5,044	5,111

PROJECT ACCOMPLISHMENTS

Wholesale Food and Cosmetics

Introduction

The Wholesale Food and Cosmetics Project is responsible for the licensing and inspection of any facility used in the production, preparation, manufacture, packaging, storage, transportation and handling of food or cosmetic items intended for wholesale distribution. Applicants are issued a license only after receiving a satisfactory inspection of the establishment location based on applicable guidelines and regulations. These guidelines and regulations include the Code of Federal Regulations and good manufacturing procedures, NJ Statutes, and the NJ Administrative Code. The Wholesale Food Project has maintained an agency contract with the FDA for completion of assigned wholesale food establishment inspections in accordance with the contract requirements. The federal contract has been renewed annually and has been in effect for more than thirty years. The 2011-2012 contract specifies inspections of 411 operations which include seafood Hazard Analysis and Critical Control Point (HACCP), juice HACCP, and various other food operations.

2011 Accomplishments

- Approximately 640 inspections and investigations were completed.
- The Project has elected to participate in the FDA Manufactured Foods Regulatory Program Standards. The Standards establish a uniform foundation for the design and management of State programs responsible for the regulation of food plants and describe best practices of a high quality food inspection program. This is an elective activity in the FDA Contract. FDA is offering States over \$100,000 to implement the Standards.
- Prior to the arrival of Hurricane Irene, FDSP sent out guidance and reminders to help the NJ food industry prepare, respond, and recover from hurricane damages as part of our joint efforts to ensure that only safe and wholesome foods enter the marketplace.
- A \$3,600 penalty letter was issued for a grocery wholesaler who was carrying misbranded dietary supplements, cosmetics, and food colorings from India. Some of the items are unapproved drugs, and the food colorings are listed on the FDA's Import Refusal list for being unapproved colors. Products identified as misbranded, adulterated, or unapproved were identified, reviewed, and voluntarily destroyed. The firm refused to provide supplier information or records, and was subsequently issued a penalty letter.
- Staff conducted a wholesale food investigation of a catering operation that revealed a number of gross insanitary conditions. During the course of the inspection, further violations were observed such as severe temperature abuse of hot food trays. Temperature-abused food was voluntarily destroyed. The FDSP inspectors issued an Unsatisfactory rating, and the firm voluntarily closed. It was found that the firm was also operating retail lunch trucks without a retail license. The county health department was notified, and also issued an Unsatisfactory rating.



PROJECT ACCOMPLISHMENTS

Certificates of Free Sale

Introduction

The Certificate of Free Sale and Labeling Unit, as part of the Wholesale Food and Cosmetics Project, routinely processes export documents and Certificates of Free Sale requests for NJ Department of Health and Senior Services licensed establishments. Typically, foreign governments request the Certificate of Free Sale as an attestation that the products being exported are of the same quality as domestic goods. It also provides an assurance that the manufacturer/distributor is in substantial compliance with State and Federal Regulations, and products are not under seizure or embargo. The coordinator reviews the product labels, product quality analysis reports, and State and Federal inspection histories for each establishment.

Historically, the coordinator of this unit would keenly evaluate food labels for health claims and structure-function claims. Labels were also reviewed for proper listing of allergenic ingredients, nutrition/supplement facts, and manufacturer/distributor information. In 2011, reviews could only consist of spot checks during busier times of the year.

Since the adoption of the Certificate of Free Sale rule in 2005, the unit has reviewed over 12,000 certificate requests, of which approximately 20% were returned for corrections. In some instances, items were embargoed due to misbranding and/or adulteration.

2011 Accomplishments

For 2011, a total of 2,381 certificate requests were processed for a total of \$125,313.

RIPPED FAST
ENERGIZE YOUR DRIVE
RIPPED FAST
FAT BURNER
120 Tablets
Dietary Supplement

Supplement Facts
Serving Size 4 Tablets
Servings Per Container: 30

Amount Per 4 Tablets	% Daily Value
Vitamin B6	100 mg 5000%
Choline	2000 mg *
Inositol	1000 mg *
L-Methionine	400 mg *
Betaine Hcl	400 mg *
L-Carnitine	100 mg *
L-Lysine	200 mg *
Lecithin	200 mg *
Linoleic Acid	200 mg *
Citric Acid	100 mg *

In a natural base of kelp
*Percent Daily Values are not established
Other Ingredients: Microcrystalline Cellulose, Magnesium Stearate, Stearic Acid, Silicon Dioxide
Lot # 063061 Exp. 07/2010

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PROJECT ACCOMPLISHMENTS

Retail Food

Introduction

The Retail Food Project is responsible for the promulgation of New Jersey's retail food rules found under N.J.A.C. 8:24-1 entitled "*Chapter 24: Sanitation in Retail Food Establishments and Food and Beverage Vending Machines.*" As such, the Project serves as the technical resource for the proper interpretation and enforcement of the retail food rules for those Health Officers and Registered Environmental Health Specialists (REHSs) employed by each of New Jersey's 100 local health departments. REHSs are charged with enforcing the retail food rules in the State's estimated 55,000 retail food establishments.

The Retail Food Project also coordinates and supervises the inspection and enforcement activities conducted by NJDHSS inspection staff of each of the retail food service facilities operating on State properties under Memorandums of Agreement (MOAs) with other New Jersey State agencies including:

NJ Department of Corrections

NJ Juvenile Justice Commission

NJ Sports and Exposition Authority

NJ Turnpike Authority

NJ Transit Corporation

NJ Division of Military and Veterans Affairs

NJ Department of Environmental Protection, Division of Parks and Forestry

NJ Department of Agriculture (Summer Lunch Program)

NJDHSS, Division of Aging and Community Services (Senior Nutrition Programs)

NJ Department of Human Services

NJ Department of Children and Families

NJ Aquarium (Camden)

In 2011, FDSP inspection staff conducted 852 retail food inspections under the MOAs.

The Project also works closely with the Department's Communicable Disease Service and affected local health departments in the coordination of the environmental investigation of food related outbreaks occurring in retail food establishments.

2011 Accomplishments

The Retail Food Project (RFP) advanced the State's Retail Food Protection activities conducted by both State and local health departments throughout New Jersey. These activities included:

- RFP co-sponsored the FDA's "Plan Review for Food Establishments" 2-day workshop at Princeton University.

- RFP met with representatives of the Ocean County Health Department (OCHD) to discuss the specifics of the NJDHSS's evaluation of the OCHD's Retail Food Protection Program. The discussions were focused on the inspection reports generated by the OCHD's inspection staff and use of the risk-based inspection form and the OCHD's anticipated participation the Retail Food Inspection Standardization Program.



PROJECT ACCOMPLISHMENTS

Retail Food (continued)

- RFP issued an update to all local health departments regarding imposter health inspectors that had been telephoning Asian style restaurants. The callers identified themselves as State health inspectors who stated that they were responding to a foodborne illness investigation and were scheduling an inspection of the restaurant. Apparently other states were reporting the same situation. In all cases the callers never appeared at the restaurant. The motive may have been to obtain credit card information from restaurants.
- RFP assisted in conducting an on-site investigation at Denville Division of Health at the request of the NJDHSS Office of Local and Public Health to investigate/verify allegations that their former health officer was remiss in fulfilling his responsibilities. The results of the investigation were submitted to the Office of Local and Public Health and a formal report was submitted to the Office of Local Health.
- RFP hosted a hearing with representatives of a local restaurant/grill to discuss pending penalty actions at a Newark Penn Station retail food establishment. This was due to continued sanitary violations cited during inspections resulting in a “Conditionally Satisfactory” rating on three consecutive inspections. At the conclusion of the hearing a penalty of \$2,500 was issued.
- RFP Coordinator provided a training program to members of the Bergen County Health Officers Association that discussed Specialized Food Processing methods conducted at the retail level.
- RFP Coordinator provided a presentation to the New Jersey Health Officers Association’s Annual Conference at the Mercer Community College Conference Center in West Windsor regarding an update of “*Retail Food Protection Initiatives.*”
 - Throughout 2011, the RFP worked closely with the Vineland City Health Department, performing audits to confirm that they have indeed become the only health agency in the nation to meet all of the FDA Voluntary Standards for Retail Food Protection. FDSP has sent a letter to FDA requesting that Vineland HD be recognized for such a monumental achievement.
 - RFP continues to hold “Best Practices for Retail Food Protection Committee” meetings. The committee, comprised of representatives from the NJDHSS, FDA, and local health departments continues its efforts to finalize the “*Best Practices for Retail Food Protection Programs in NJ*” manual and develop other pertinent information to enhance retail food protection programs carried out by local health departments throughout NJ.



- RFP has been developing a “Chapter 24 Rules Revision Committee” to discuss proposed changes to the Chapter 24 “Sanitation in Retail Food Establishments and Food and Beverage Vending Machines” (N.J.A.C. 8:24) that is scheduled to sunset on January 2, 2014. The Committee will be comprised of representatives from NJDHSS, FDA, local health departments, NJ’s retail foodservice and retail food associations, and academia.

PROJECT ACCOMPLISHMENTS

Retail Food (continued)

Risk-based Inspection Standardization

The RFP, in following guidance from FDA, is committed to enhancing the effectiveness of the inspection of retail food establishments in NJ through the promotion of the Risk-based Retail Food Inspection approach. The goal of this new inspection approach is to enable inspectors to better identify and control the recognized “Foodborne Illness Risk Factors” that are responsible for foodborne illness outbreaks. These factors include: poor personal hygiene by food workers; holding foods at improper temperatures; inadequately cooking meat, poultry, eggs and fish; contaminated equipment; and using foods from unsafe sources.

Towards this goal the RFP:

- Continues to update the “Risk-Based Retail Food Inspection Handbook” containing all of the documents necessary to complete a retail food inspection report using the risk based inspection.
- Continues to conduct “field standardization training” of REHSs from local health and county departments. In 2011, an additional 7 REHSs from Gloucester, Warren, Middlesex, Burlington counties and Hoboken Health Department participated. To date, 23 REHSs have completed the standardization program in 12 counties.
- Conducted their second annual meeting for all Certified Retail Food Specialists. The participants comprised representatives from nine local health departments who have been ‘standardized’ to train other REHSs to perform standardized risk based retail food inspections. This provided an opportunity for the experienced trainers and the newly trained Standards to meet each other provide comments and share their training experiences. General topics of the meeting included the progression of the Retail Food Inspection Field Standardization process, report writing, enforcement, and their plans to further the Standardization process in their jurisdictions and beyond.

Live Bird Markets

FDSP spent the first three months of 2011 visiting live poultry markets in order to develop guidance for sanitary operations for those local health officials responsible for the Inspection of these facilities.

Towards this goal the RFP:

- Provided a presentation entitled “How Chicken Little Became Campylobacter Casserole” to local health department epidemiologists at the request of the Infectious Disease Unit Coordinator.
- Provided a presentation entitled “How To Inspect Live Bird Markets” to local health inspectors at the NJEHA annual conference. The presentation involved instructing them how to inspect live bird markets.

- Began the process of developing a guidance document for local health departments to familiarize them with the operations of live bird markets and instructions regarding inspections.



PROJECT ACCOMPLISHMENTS

Seafood and Shellfish

Introduction

Under the Seafood and Shellfish Project, wholesale shellfish dealers who handle, process, and ship shellfish are required to maintain sanitary conditions and retain documentation verifying that the shellfish were obtained from approved harvest areas. The surge in consumption of seafood and shellfish has led to a growth in the number of establishments requiring inspections. Inspectors routinely inspect all certified shellfish wholesalers (approx. 150) biannually, quarterly, and monthly as required under strict, nationally recognized criteria known as the Model Ordinance and adopted by reference in the shellfish rule N.J.A.C. 8:13.

2011 Accomplishments

The FDA was pleased to report to the NJDHSS that the NJ Seafood/Shellfish Project was found to be in substantial conformance, effectively implementing and enforcing the shellfish program requirements including HACCP implementation, time temperature control, sanitation and recordkeeping. In their report, the FDA noted that Project personnel have “continued to work hard to meet and whenever possible to exceed” requirements by closely monitoring conditions at certified shellfish firms at the required frequencies and conducting reinspections with corrections accomplished. In addition, the FDA evaluated the 2011 implementation of a risk reduction plan for the prevention of *Vibrio* parahaemolyticus (Vp) illnesses from the consumption of raw oysters from New Jersey and found that the project was closely monitoring the handling, refrigeration, and storage of these products in determining compliance with the National Shellfish Sanitation Program and the Vp control plan. Furthermore, the FDA congratulated staff for their efforts at providing training and educational opportunities for consumers and the regulated industry regarding the safeguards necessary to prevent illnesses from consumption of shellfish including post-harvest temperature reduction during warm weather.

Emergent Activities

Due to Hurricane Irene and then the added inundating rainfall from Hurricane Lee, all shellfish harvest beds were presumptively closed before the Labor Day weekend by the New Jersey Department of Environmental Protection (NJDEP) previous to the storm occurring. In total, seven states on the eastern seaboard closed most of their shellfish waters as well. The NJDEP continued daily water testing of shellfish waters during the closure to determine elevated fecal coliform levels which were posted daily on their website. Conference calls were held by the NJDEP, NJDHSS, the two shellfisheries councils, and industry in order to communicate the ongoing water quality concerns. The NJDHSS Seafood/Shellfish Project received, managed and handled numerous continuous daily phone calls from industry in order to communicate the water quality results. In addition, NJDHSS field inspectors were dispatched to ascertain if any product was being distributed from closed waters as well as to prevent any commingling of closed product. Another NJDHSS field inspector worked attentively with the depuration plants on site to manage and secure proper processing of product subsequent to reopening and the occurrence of low salinity due to dilution. These two catastrophic events closed NJ shellfish waters from August 27th through the beginning of October, causing damage to fishing vessels, removing entire banks of the Delaware River, and flooding certain shellfish establishments.



PROJECT ACCOMPLISHMENTS

Food Defense and Emergency Preparedness

Introduction

The Food Defense Project coordinates the protection of New Jersey's food supply from intentional adulteration based on Presidential Homeland Security Directives and the Bioterrorism Act of 2002, as well as other emergency situations such as floods and blackouts. This project is responsible for defining the Critical Infrastructure within the food sector, disseminating and monitoring the implementation of the Food Sector Best Practices, and providing training programs for industry and public health officials. This project also assists industry in conducting site-specific vulnerability assessments and development of emergency response plans.

Unfortunately, FDSP's wholesale food defense field activities (vulnerability assessments) were reduced from 541 in 2010 to 30 in 2011.

2011 Accomplishments

A 50-state teleconference was held in response to the nuclear disaster in Japan. The U.S. Environmental Protection Agency (EPA) and FDA confirmed that slightly higher than normal levels of radioisotopes, released into the atmosphere from the severely damaged Fukushima Daiichi nuclear reactor in Japan, had been detected in rainwater in several states, as well as in milk samples from California, Washington, Saipan, Guam, Alaska, and Hawaii. NJDHSS field staff obtained and provided the requested samples of whole milk, produced by widely-consumed brands from different plants throughout NJ, NY, and PA. NJDHSS was then contacted by NJDEP to provide a subsequent round of samples, which was done immediately. All sampling results were determined to be "non-detected."

Prior to the arrival of Hurricane Irene, FDSP sent out guidance and reminders to help the NJ food industry prepare, respond, and recover from hurricane damages as part of joint efforts to ensure that only safe and wholesome foods enter the marketplace. As a follow-up to Hurricane Irene and subsequent storms, 10 FDSP staff members volunteered to work with Local Health Departments (LHDs) to provide guidance regarding retail food establishments operating under limited operations because of damages from the hurricane. The FDSP had more volunteers than any other service program. Staff members provided much-needed information and advice to members of the public on topics such as food/water safety, mold remediation, carbon monoxide detection, sewage spill clean ups, and sanitation of household items that came into contact with sewage water. Staff worked approximately 10 hours per day at the centers. They also provided direct assistance by conducting retail food inspections for LHDs. They worked side by side with the Office of Emergency Management (OEM), and the regulated food industry following the activation of Operation Food Distribution (OFD) as part of the State's Emergency Operations Plan. The purpose of OFD is to feed the public following a widespread emergency by using the private sector. This Operation is a great example of the public and private sector working in partnership to serve the needs of the public.



PROJECT ACCOMPLISHMENTS

Food Defense and Emergency Preparedness

(continued)

A team of inspectors conducted food defense activities before and during a nationally televised football game on September 11 at Met Life Stadium, identified by the FBI as a potential target for terrorist attack. This food defense initiative focused only on food defense concerns associated with in-State and out-of-State wholesale food establishments supplying food to the Stadium and the food services within the Stadium. The week before the game, several FDSP staff and FDA met with key Stadium officials and the FBI to discuss food defense issues. The reason for the visit and concerns about food defense during a game of such national attention were explained. Staff also discussed the importance of food defense self-assessments and provided the necessary materials and background for implementing the self-assessments. FDA explained the federal government's concerns about food defense and federal initiatives including the ALERT and FIRST training programs. A walk through of the Stadium following the flow of food from arrival through preparation and sale/distribution was conducted. Vulnerabilities were discussed and recommendations were provided.

FDSP discussed food defense with corporate and the foodservice management company, conducted three on-site visits to assess food defense vulnerabilities, and provided recommendations to key management personnel. FDSP inspectors also conducted investigations of the Stadium's wholesale suppliers.



PROJECT ACCOMPLISHMENTS

Dairy, Juice, and Bottled Water

Introduction

This Project licenses and inspects in-state and licenses out-of-state wholesale milk, frozen dessert, bottled and bulk water processors, and ensures that in-state juice processors adhere to the provisions of 21 CFR Part 120. The Project also regulates and inspects wholesale establishments which produce cheese products and inspects dairy farms which supply raw milk to Grade A Interstate Milk Shipper-listed milk plants. The Project serves as the regulatory agency for ratings and enforcement of the Pasteurized Milk Ordinance (PMO), the nationally-adopted standard of sanitation regulations applicable to Grade A milk plants engaged in interstate commerce. Field staff inspect New Jersey's milk plants quarterly and sample their products monthly. In-state and out-of-state bottled/bulk water processors and frozen dessert processors are required to be licensed. Juice processors are licensed as non-alcoholic beverage establishments and are required to have a validated Hazard Analysis and Critical Control Point (HACCP) plan for pathogen reduction.

In previous years, bills to allow for the sale of raw milk to consumers were proposed in the Legislature, with little support. In 2011, increased support among legislators resulted in the passage of A2702, A Bill to Permit Sale of Raw Milk Under Certain Conditions and Establishes Raw Milk Permit Program, in the General Assembly. The bill was then referred to the Senate Economic Growth Committee where it was heard, but not voted on before the legislative session terminated. The bill has been proposed again for the 2012 Legislative Session. This Project has submitted an enormous amount of documentation and evidence in opposition of this bill in order to protect public health.

In 2011, 33 bottled water brands were sampled, one of which exceeded the maximum contaminant level for arsenic. A few brands were found to exceed secondary drinking water standards, which relate to aesthetic issues. Two consumer complaints regarding milk and bottled water products were received and investigated, with inconclusive results. Sustained aggressive enforcement of state and federal dairy and bottled water standards has greatly reduced the frequency of encountering noncompliant products.

2011 Accomplishments

- Completed 277 inspections of wholesale bottled water, dairy, frozen dessert, and juice processors
- 854 samples were obtained and submitted for laboratory analysis
- Participated in accelerated surveillance of packaged milk products for radiation after fallout from the severely-damaged Fukushima Nuclear Power Complex in Japan. All samples tested were negative.
- Investigated the September 9, 2011 theft of three trucks loaded with packaged milk products. The heightened security preceding 9/11/11 increased the urgency, resulting in the mobilization of many local and state health department staff members to monitor food establishments for the presence of the stolen milk. The trucks were found abandoned, but none of the milk was ever recovered.



PROJECT ACCOMPLISHMENTS

Dairy, Juice, and Bottled Water

(continued)

- Embargoed or oversaw voluntary destruction of more than 54,977 gallons of bottled water and dairy products combined
- Licensed 17 new water bottlers and bulk water sources to sell in New Jersey, including 4 foreign bottlers
- Investigated 5 dairy, bottled water, frozen dessert, and non-alcoholic beverage complaints
- Identified 7 bottled water firms distributing their products in New Jersey without a license
- Identified 15 occurrences of milk testing positive for antibiotics, totaling 519,104 pounds; oversaw the destruction of these products



PROJECT ACCOMPLISHMENTS

Wholesale Drug

Introduction

The NJDHSS requires registration of wholesale drug distributors that distribute drugs into New Jersey. In 2011, the Project issued 1,545 drug and medical device registrations to manufacturers, distributors, re-labelers, re-packers, and brokers of wholesale prescription and over-the-counter drugs. In 2011, approximately 250 initial applications were received. In addition, 2,092 drug verifications of good standing were received and completed for industry, which represents almost a 3.3 fold increase from 2006. The Wholesale Drug Project has developed an E-Verification system to handle these numerous requests. Amendments in the current regulation, Title 24 – Food and Drugs, were previously adopted to strengthen the provisions as they relate to combating and counterfeit and diverted drugs, as well as concerns regarding criminal activity and violation disclosures. An added effort has been initiated to respond to industry complaints and other states' filed complaints regarding illegitimate drug companies.

The adopted rules are necessary to protect consumers from adulterated, misbranded, and counterfeit medical devices, and over-the-counter and prescription drugs. Counterfeit drugs often involve cancer drugs, cardiovascular medication, and “lifestyle” drugs with the deliberate intent of deceiving consumers as to the nature and effect of the drug. The internet has allowed a large breeding ground for the increase of counterfeit drugs, but it is not the only cause of this increase. Weak distribution oversight allows counterfeiters to easily penetrate all aspects of the drug distribution supply chain. The domestic value of counterfeit pharmaceutical seizures by U.S. Customs in FY 2011 rose by more than \$11 million, an increase of almost 200%. China, India, and Pakistan remain the top three source countries for counterfeit pharmaceuticals. In 2012, it is projected that global counterfeit sales will reach 75 billion dollars.



FOOD SAFETY EDUCATION AND OUTREACH

Introduction

The Food and Drug Safety Program (FDSP) creates high-quality educational outreach materials that communicate important safety and health messages to various audiences such as the food/drug/cosmetic industry, the regulatory community, and the public. These educational materials are routinely promoted and distributed at events such as conferences and seminars, and by local health departments, who assist in distributing the materials to retail establishments and the general public. The FDSP website, redesigned and launched in 2009, displays all of the Program's educational outreach materials.

Educational efforts also include partnerships with food safety organizations, agencies, or other health departments. These valuable partnership opportunities enable the FDSP to reach out to and promote messages to populations or operations that are not easily accessible otherwise. Partnerships have also promoted interagency sharing of expertise and resources that enhance the efforts of all involved, and continue to help the FDSP build trust and maximize teamwork.

2011 Accomplishments

FDSP Partners With FDA to Promote the Oral Culture Educational Project

A FDSP-FDA partnership was formed to explore outreach strategies regarding the FDA's Oral Culture Project multi-lingual educational posters (see poster example, insert). The posters are geared towards non-English speaking food workers who originate from oral cultures, that is, cultures that rely upon storytelling for communication of important messages. The goal of the outreach efforts is to increase exposure of the posters to local health departments and retail food establishments. The 7 posters, which are available in 7 languages, focus on raising awareness of the impact of food handling practices related to personal hygiene and employee health. They are also intended to help food employees understand the reasons why following good food safety practices is important to preventing illness, death and loss of income and reputation from food-related outbreaks.

The FDSP was awarded \$3,750 by FDA for the project. This funding is being utilized to purchase 500 flash drives which contain all 7 posters in 7 languages. The flash drives will facilitate dissemination of the posters to retail food establishments. They will be distributed to local health inspectors for direct dissemination to food establishments.

FDSP Gains Valuable Insight From the Ill Food Service Worker Project

A FDSP staff member oversaw the ill food service worker project, intended to understand ill food worker policies and practices in retail food establishments.

Researchers sought to use this information to develop targeted educational outreach materials on the topic. The project was developed and implemented by a graduate student, and completed at the New Jersey Environmental Health Association (NJEHA) conference. 30 Registered Environmental Health Specialists (REHSs) were interviewed. It was found that the most common barriers to implementing ill food worker policies include language, belief that policies are not important, and fear of repercussions. The results will assist the FDSP in understanding how to design educational outreach materials on the topic of ill food service worker policies, behaviors, and practices.

Outreach to Media

FDSP worked with the NJDHSS Communicable Disease Service to issue several press releases regarding food safety for the holidays and food safety during summer activities.

जो कुछ मेरे साथ हुआ उसे अपने साथ न होने दें



हमेशा लोगों की सुरक्षा करें। अपने हाथ धोयें, दाढ़्यां या चम्मच का इस्तेमाल करें और जब कभी भी आप बीमार हों, काम न करें।

“Don't Let What Happened to Me, Happen to You” (Hindi)

FOOD SAFETY EDUCATION AND OUTREACH (continued)

FDSP Staff Becomes First in State to Take On-Line FDA Courses

FDSP licensed inspection staff became the first in the state to take on-line FDA courses for continuing education credits. FDSP is the first Program within a regulatory agency in NJ to set up and implement this initiative, and will act as the model for local health departments to begin a similar program. The curriculum consists of a series of 38 on-line courses in topics such as food additives, pasteurization, microbiological control, and foodborne illness investigations. FDSP inspectors who conduct FDA contract inspections are now required to complete all of these courses in order to fulfill contract requirements. These courses are required, but under this new initiative inspection staff will also receive continuing education credits that can be applied towards annual licensure credit requirements.

FDSP Promotes Food Allergy Awareness

In conjunction with Governor Christie's proclamation, the FDSP issued a press release to announce Food Allergy Awareness Week in May. The press release informed consumers about the seriousness of food allergies, and how the FDSP is working to promote awareness of food allergies and prevention of food allergic reactions. It also included information on how FDSP inspections routinely review labels for accurate food allergy information. The FDSP also promoted the bi-lingual educational poster, "Food Allergies; It's a Matter of Life or Death" to local health departments for distribution to food establishments.

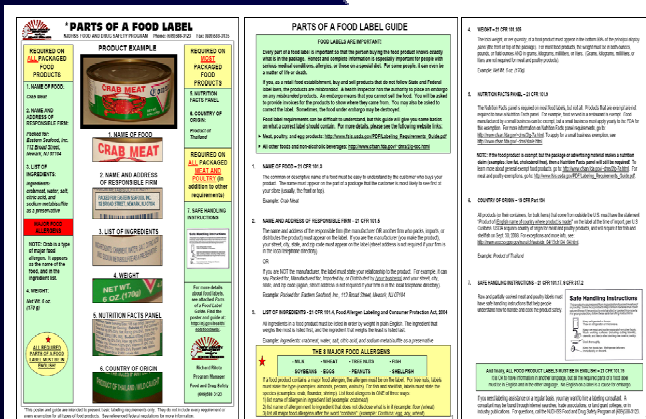
Numerous local school districts and several local health departments responded to the press release by requesting copies of the posters. A total of 4,800 posters were distributed around the state as a result of this press release. The posters are intended to raise food handlers' awareness of food allergies and prevention/response efforts. This poster has been distributed in every county in NJ and requests for additional posters continue on a regular basis.

FDSP Staff Educational Presentations

A staff member delivered a presentation on food labeling at a NJ Dietary Manager's Association (NJDMA) seminar. Topics discussed included food labeling issues, specific requirements of a food label, and labeling hot topics. The participants were also introduced to the educational material, "Parts of a Food Label," a 3-page poster and guide that simplifies food labeling requirements. About 70 participants (including dietary managers from schools, hospitals, daycare, prisons, etc.) were in attendance.

Two staff members delivered a presentation on dietary supplements and herbal

remedies at the University of Medicine and Dentistry (UMDNJ). The presentation introduced participants to the scope of current good manufacturing practices (cGMPs). Participants included local Health Officers, Registered Environmental Health Specialists, and other health professionals. The discussion included an overview of imported products found in NJ that have caused harm or are potentially harmful. FDSP regulatory action was discussed as the participants were taken step by step through an actual investigation of a harmful product. About 30 participants were in attendance.



MAJOR BOARDS AND COUNCILS

New Jersey Infrastructure Advisory Committee (IAC)

Mr. Richard Ritota, Government Liaison - Food Sector

This Committee serves as a subgroup of the New Jersey Domestic Security Preparedness Task Force. Its members consist of private sector chairs of each of the infrastructure sectors along with those New Jersey agencies having a significant responsibility to protect one or more sectors.

New Jersey Produce Safety Task Force

Mr. Richard Ritota, NJDHSS representative membership

Formed in January 2007, the Produce Safety Task Force is committed to improving the food safety of products grown and distributed throughout New Jersey. Members include NJ Department of Agriculture staff, farmers, Rutgers Cooperative Extension, Rutgers Food Policy Institute, NJ Restaurant Association, and NJ Food Council.

New Jersey Aquaculture Council

Mr. Douglas Fisher, Secretary – NJDOA – Chairman

Mr. Richard Ritota, NJDHSS, representing Commissioner Mary O'Dowd

Ms. Cali Alexander, NJDHSS, alternative representative

New Jersey Toxics in Biota Committee

Mr. Richard Ritota, NJDHSS, representing Commissioner Mary O'Dowd

Ms. Cali Alexander, NJDHSS representative

Interagency committee consisting of NJDEP, NJDHSS, and NJDOA

New Jersey Interstate Environmental Committee

Mr. Richard Ritota (and Joseph Eldridge as the alternate) representing Commissioner Mary O'Dowd

The mission of this Committee is to protect and enhance environmental quality through cooperation, regulation, coordination, and mutual dialogue between government and citizens in the tri-state region (Connecticut, New York, and New Jersey).

New Jersey Food Sector Work Group

Mr. Richard Ritota, NJDHSS Representative

This work group primarily addresses food defense and food emergency preparedness. Members include FDA, OHSP, New Jersey food associations, and the food industry.

Best Practices for Food Protection Committee

William Manley, NJDHSS, Chair

The committee is comprised of representatives from NJDHSS, FDA, and local health departments.

The New Jersey Retail Rulemaking Committee

William Manley, NJDHSS, Chair

This committee includes the New Jersey Food Council, the New Jersey Restaurant Association, and the retail food industry.